

## **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the remarks that follow.

### ***I. Claim Status***

Claims 1-4 and 9-14 are withdrawn. Claims 5, 7-8 and 15-18 are cancelled presently, without prejudice or disclaimer, and claims 19-25 are added. No claims are amended. Support for these revisions are evident throughout the specification. Thus, support for new claims 19 and 25 can be found on page 4, line 16 – page 6, line 28 and page 7, line 21 – page 10, line 5, support for new claim 20 can be found on page 5, lines 1-3, page 7, lines 28-32 and page 13, line 1 – page 31, line 5, support for new claim 21 can be found on page 7, lines 28-32, support for new claim 22 can be found on page 27, line 3 – page 28, line 35 and Figure 15, support for new claim 23 can be found on page 4, line 32 – page 5, line 1 and support for new claim 24 can be found on page 4, lines 5-7. No impermissible new matter is added, therefore.

Upon entry of the amendment, claims 1-4, 9-14 and 19-25 will be pending and subject to examination on the merits.

### ***II. Section 102 Rejections To Claims 5, 7-8 and 15-18 Should Be Withdrawn***

Claims 5, 7-8 and 15-18 are rejected for alleged anticipation by Sair, U.S. 4,230,687. The present cancelation of claims 5, 7-8 and 15-18 renders these rejections moot, however.

### ***III. New Claims 19-25 Are Patentable***

The various grounds of rejection lodged against the canceled claims are inapposite to the present claims, including independent claims 19 and 25. Claim 19 is directed to a material for encapsulating a therapeutic and nutritional agent, which is storage unstable. Claim 25 is directed to an encapsulated therapeutic and nutritional agent, which is storage unstable, that is encapsulated by an encapsulating material.

The material of claim 19 includes “(A) a pre-processed starch; and (B) a film forming protein” and the “pre-processed starch and the film forming protein form a protective shell around the therapeutic and nutritional agent, that allows release of the therapeutic and nutritional

agent in the gastrointestinal tract.” The encapsulated material of claim 25 includes similar elements to the previously recited elements of claim 19. The starch is pre-processed to break down long starch molecules, so as to make emulsions of an encapsulant material stable, and to increase the number of sugar reducing groups in the starch. When the pre-processed starch is combined with the film-forming protein in an aqueous solution and this combination is mixed with the therapeutic or nutritional agent, an emulsion is formed that protects the agent against early uptake and metabolism in the stomach and upper gastrointestinal (GI) tract. If the material does not include the pre-processed starch and the film forming protein the agent will not reach the GI tract because it will not be protected against early uptake and metabolism.

The examiner relies on Sair to disclose “an encapsulation material comprising casein as a protein and modified starch Capsul as a treated carbohydrate” (Office Action at 2). The examiner acknowledges that the method disclosed in Sair is not the same as the claimed method, but contends that “the materials produced by both [Sair and the claimed invention] are necessarily the same and would be capable of releasing [an] active [agent] in a predetermined location in the in the gastrointestinal tract” (*id.* at 5).

Yet, as evidenced by the accompanying Declaration Under 37 C.F.R. § 1.132 of Mary Ann Augustin (“Augustin Decl.”), Sair does not disclose a material for encapsulating a therapeutic and nutritional agent that comprises (A) a pre-processed starch and (B) a film forming protein as posited by the examiner. As attested by the declarant, an expert in the relevant field, Sair discloses “different materials [from the claimed invention] to form the encapsulant” as “Sair speaks of using a chemically treated carbohydrate, a gum **or** a protein as the encapsulant material” (Augustin Decl. ¶ 7). The declarant further attests that, although “[e]xample 8 [of Sair] relates the use of a carbohydrate and protein,” the reference “does not disclose or suggest ... that the soy flour of the example or any other carbohydrate is a pre-processed starch” (Augustin Decl. ¶ 7). In fact, the declarant attests that “a knowledgeable reader of Sair would not find there any disclosure implicating a pre-processed starch” (*id.*).

Further, the examiner contends that as the “encapsulation material disclosed by Sair et al. comprises the same components as the encapsulation material recited in the instant claim, thus the encapsulation material disclosed by Sair et al. would necessarily possess the same release property as that of the encapsulation material recited in the instant claim” (Office Action at 3).

Yet, as additionally evidenced by the Augustin Declaration, Sair fails to disclose a material that allows release of the therapeutic and nutritional agent in the gastrointestinal tract. To the contrary, "Sair only discloses releasing an active agent in the mouth" (§ 8). Moreover, the active agent in Sair cannot reach the GI tract because Sair discloses "a different procedure to form the encapsulating material than the captioned application" (*id.*, § 9). In particular, "Sair requires high temperature to melt the matrix prior to forming a sticky mass at very high viscosity in which the active agent, to be encapsulated, is dispersed" (*id.*).

Because Sair uses a different procedure, "Sair does not provide the core/shell type protective encapsulation that is achieved by the claimed invention" and "[a]s a result, the lack of pre-processed starch in Sair prevents the active agent from reaching the GI tract and instead only allows release of the active agent in Sair in the mouth" (*id.*). Accordingly, a rejection against claims 19 and 25 cannot stand, validating their patentability. Dependent claims 20-24 likewise are patentable over the art of record.

### CONCLUSION

Applicants submit that this application is in condition for allowance, and they request an early indication to this effect. Examiner Yu also is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

Respectfully submitted,

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